HEMOSIL®
THROMBOPHILIA ASSAY PANEL

A complete solution

when comprehensive testing is key



werfen

Accurate and Comprehensive Thrombophilia Testing

Thrombophilia can be attributed to many factors, necessitating testing that is not only accurate, but comprehensive.

The HemosIL Thrombophilia Assay Panel delivers

- **Clinical utility**
- **Automation**
- **Stability**

Standardized across the ACL TOP® Family and ACL TOP Family 50 Series Hemostasis Testing Systems.



Thrombophilia: tendency, either inherited or acquired, to develop thrombosis.

One solution for identification of risk factors for venous thromboembolism

Thrombophilia assays

Inherited

Liquid Antithrombin
- Factor Xa-based assay for the quantitative determination of antithrombin (AT)
- Liquid, ready-to-use
- No interference from heparin cofactor II up to 4 U/mL

Protein C
- Chromogenic assay for the quantitative determination of protein C (PC)
- Broad linearity
- Excellent on-board stability

ProClot
- Functional clot-based assay for the quantitative determination of PC
- Complements HemosIL Protein C

Protein S Activity
- Functional clot-based assay for the quantitative determination of protein S (PS) activity
- Human recombinant tissue factor and synthetic phospholipids for lot-to-lot consistency

Free Protein S
- Latex immunoassay for the quantitative determination of PS
- No interference from Factor V Leiden (FVL) mutation
- Extended three-month calibration stability

Factor V Leiden (APC R V)
- Clot-based assay for the determination of resistance to activated PC caused by FVL
- >99% sensitivity for FV:Q506 mutation
- Not affected by vitamin K antagonist (VKA) therapy or heparin present in plasma samples (up to 1 U/mL)

Acquired

dRVVT Screen and dRVVT Confirm*
- Integrated assay for the qualitative detection of lupus anticoagulant (LAC)
- dRVVT method recommended by The International Society on Thrombosis and Haemostasis (ISTH) Scientific and Standardization Committee (SSC)1
- Excellent on-board and refrigerated stability

Silica Clotting Time (SCT)*
- Silica-based screening assay sensitive to phospholipid-dependent antibodies for the qualitative detection of LAC
- ISTH SSC recommends silica-based APTT reagents for LAC testing1
- Liquid formulation, ready-to-use

Mixed/Unknown

Homocysteine
- Latex-enhanced immunoassay for the quantitative determination of total L-homocysteine
- Automatically measures homocysteine in three stages
- Linearity up to 60 µmol/L

FVIII Deficient Plasma
- FVIII deficient plasma for the determination of FVIII activity when used with APTT reagents
- FVIII deficient plasmas available with or without normal levels of von Willebrand factor activity

HemosIL® ASSAYS

*HemosIL LA assays (dRVVT, SCT), together with the HemosIL AcuStar aPL assay panel, provide a complete solution for antiphospholipid syndrome testing.

Risks and traits

Venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), is a common sequelae of thrombophilia.

Conditions associated with increased risk of VTE[2-4]

Inherited	Acquired	Mixed/Unknown
• AT deficiency • PC deficiency • PS deficiency • FVL • Prothrombin G20210A mutation • Dysfibrinogenemia	• LAC/antiphospholipid syndrome • Pregnancy, oral contraceptive therapy, hormone replacement therapy • Immobilization • Previous thrombosis • Age • Surgery, malignancy • Myeloproliferative disorders	• Hyperhomocysteinemia • Elevated levels of: - FVIII, FIX, FXI - Prothrombin - Thrombin-activatable fibrinolysis inhibitor (TAFI) - Tissue factor pathway inhibitor (TFPI) • Activated PC resistance in the absence of FVL

Prevalence of Inherited Thrombophilia and VTE[5,6]

Trait	Prevalence in general population	Prevalence in patients with VTE
AT deficiency	0.02%	1%
PC deficiency	0.2%	3%
PS deficiency	0.03–0.13%	2%
FVL	3–7%	20%
Prothrombin 20210A mutation	0 .7– 4%	5%

up to **50%**

of patients with unprovoked VTE have an underlying thrombophilia

Testing for thrombophilia[7,8]

Why?

- Identify individuals at risk for recurrent thrombosis
- Test results may inform clinical decisions
- Enables appropriate counseling in selected patients

When?

- At least six weeks after an acute thrombotic episode
- After the effects of anticoagulant treatment are no longer present

Who?

- Patients presenting with VTE at an early age (<40 years) and with family history of thrombosis
- Pregnant women at risk for thrombosis
- Children with purpura fulminans

Consistent performance and automated efficiency, test after test

HemosIL Thrombophilia Assay Panel

Product	Part Number	Kit Configuration
Liquid Antithrombin	0020002500	**ACL Elite®/ACL Elite Pro** 4 x 4 mL FXa Reagent (liq), 2 x 2 mL Chromogenic Substrate, S-2765 (liq)
	0020030100	**ACL TOP Family/ACL TOP Family 50 Series** 4 x 4.5 mL FXa Reagent (liq), 4 x 4.5 mL Chromogenic Substrate, S-2765 (liq)
	0020300400	**ACL TOP Family/ACL TOP Family 50 Series** 2 x 2 mL FXa Reagent (liq), 2 x 2 mL Chromogenic Substrate, S-2765 (liq)
	0020300440	**ACL TOP Family/ACL TOP Family 50 Series** 4 x 2 mL FXa Reagent (liq), 4 x 2 mL Chromogenic Substrate, S-2765 (liq)
Factor V Leiden	0020008700	2 x 4 mL APTT Reagent (liq), 2 x 4 mL Factor-V Reagent Plasma (lyo), 2 x 2 mL APC/$CaCl_2$ (lyo), 2 x 2 mL $CaCl_2$ (liq), 2 x 1 mL APC Control Plasma Level 1 (lyo), 2 x 1 mL APC Control Plasma Level 2 (lyo)
Protein C	0020300500	2 x 2.5 mL Protein C Activator (lyo), 2 x 2.5 mL Chromogenic Substrate, S-2366 (lyo), 1 x 8 mL Diluent (liq)
ProClot	0008468310	4 x 1.5 mL Protein C Activator (lyo), 4 x 1 mL Protein C Deficient Plasma (lyo), 2 x 1 mL Protein C Control Plasma (lyo)
Protein S Activity	0020302000	3 x 2 mL Protein S Reagent (lyo), 2 x 6 mL Calcium Reagent (liq), 3 x 2 mL Protein S Deficient Plasma (lyo)
Free Protein S	0020002700	3 x 4 mL C4BP Buffer (liq), 3 x 4 mL C4BP Latex (lyo), 3 x 2 mL Anti PS mAb Latex (lyo)
Homocysteine	0020007800	2 x 2 mL a-SAH Latex Reagent (lyo), 2 x 2 mL Reductant (liq), 2 x 2 mL Enzyme (liq), 2 x 2.5 mL Conjugate (liq), 2 x 9 mL Buffer (liq), 2 x 1 mL Calibrator (liq)
dRVVT Screen **dRVVT Confirm**	0020301500 0020301600	10 x 2 mL dRVVT Screen (lyo), 10 x 2 mL dRVVT Confirm (lyo)
Silica Clotting Time	0020004800	3 x 5 mL SCT Screen (liq), 3 x 5 mL SCT Confirm (liq), 3 x 10 mL SCT $CaCl_2$ (liq)
LA Negative Control **LA Positive Control**	0020012500 0020012600	10 x 1 mL (lyo), 10 x 1 mL (lyo)

HemosIL® ASSAYS

HemosIL Thrombophilia Assay Panel

Accurate and comprehensive thrombophilia testing

- Clinical utility
- Automation
- Stable



References

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4. Rosendaal FR. Venous thrombosis: the role of genes, environment, and behavior. *Hematology Am Soc Hematol Educ Program.* 2005;1–12.
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6. Middeldorp S. Inherited thrombophilia: a double-edged sword. *Hematology Am Soc Hematol Educ Program.* 2016;2016(1):1–9.
7. Cohoon K, Heit J. Inherited and secondary thrombophilia. *Circulation.* 2014;129(2):254–7.
8. Baglin T, Gray E, Greaves M, *et al.* Clinical guidelines for testing for heritable thrombophilia. *Br J Haematol.* 2010;149:209–20.

IL is passionate about bringing the most innovative solutions to Hemostasis testing. Offering a broad range of the highest quality instruments, data management solutions and a full panel of HemosIL assays supported by a world-class technical team, Werfen is committed to enhancing patient care through continuous innovation.

Werfen
Corporate Headquarters
Plaza de Europa, 21–23
08908 L'Hospitalet de Llobregat
Barcelona, Spain
+34-93-4010101
werfen.com

Instrumentation Laboratory Headquarters
180 Hartwell Road
Bedford, MA 01730 USA
+1-781-861-0710
instrumentationlaboratory.com

Worldwide Locations

The Americas

Brazil
São Paulo
+55-11-46227878
br.werfen.com

Canada
Richmond Hill, ON
+1-800-552-2025 x6115
instrumentationlaboratory.com

Colombia
Bogotá
+57 15 221 052

Mexico
Mexico City
+52-55-5262-1760
mx.werfen.com

Uruguay
Montevideo
+5982-481-81-33

USA
Bedford, MA
+1-781-861-0710
instrumentationlaboratory.com

Asia-Pacific

Australia
Sydney
+61-02-9098-0200
au.werfen.com

China
Beijing
+86-10-59756055
Hong Kong
+852-2792-7773
Shanghai
+86-21-66308671
cn.werfen.com

India
New Delhi
+91-490-29-550
in.ilwerfen.com

Japan
Tokyo
+81-3-5419-1301
jp.werfen.com

Korea
Seoul
+82-1899-9217
kr.werfen.com

Thailand
Bangkok
+66-271-226-28/9

Europe

Austria
Vienna
+43-1-256-58-000
at.werfen.com

Belgium
Brussels
+32-2-7252052
benelux.werfen.com

Czech Republic
Prague
+420-246-090-931
cz.werfen.com

France
Paris
+33-182-30-86-00
fr.werfen.com

Germany
Munich
+49-89-909070
de.werfen.com

Hungary
Budapest
+36-1-882-73-10
hu.werfen.com

Italy
Milan
+39-02-25221
it.werfen.com

Lithuania
Kaunas
+370-37-313157
lt.werfen.com

The Netherlands
Breda
+31-76-5480100
benelux.werfen.com

Poland
Warsaw
+48-22-336-18-00

Portugal
Lisbon
+351-214247312
pt.werfen.com

Russia
Moscow
+7-499-124-45-59
ru.ilwerfen.com

Spain
Barcelona
+34-902-20-30-90
es.werfen.com

UK
Warrington, England
+44-1925-810141
uk.werfen.com

For all other countries visit
international.werfen.com

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